REMARKS

Status of the Claims

Claims 1-4, 15-33 and 46-60 were pending in the application.

Claims 1-4, 15-33, and 46-60 were rejected.

Claims 15, 28, 51 – 54, and 57-60 have been amended. Claims 1-4, 16-20, 22-27, 31 – 50, 55, and 56 have been canceled.

Upon entry of this amendment, claims 15, 21, 28 – 30, 51 – 54, and 57-60 will be pending.

Summary of the Amendment

Claims 15, 51 – 54, and 57-60 have been amended to delete non-elected subject matter and present the claims in a more precise manner. Support for the amendments can be found throughout the specification and originally filed claims.

Claim 20 has been amended to correct its dependency on newly amended claim 15.

Claim 15 has been amended to recite statutory subject matter in better comport with 35 U.S.C. §101. Support for this amendment appears on page 47, lines 15-17, of the specification.

Claims 15 and 28 have been amended to recite more definite subject matter. Support for the amendment is found on page 71 of the specification and throughout the originally filed claims.

Information Disclosure Statement

The disclosure statement filed on June 15, 2005 has been objected to because the statement does not comply with the 37 C.F.R. § 1.98(d). The Office asserts that the disclosure statement fails to indicate in which of the two previously filed applications copies of each of the cited references can be found. Applicants have prepared and resubmitted a disclosure statement adequately identifying U.S. Patent Application No. 10/213,821, filed August 6, 2002 and U.S. Patent Application No. 10/283,423, filed October 30, 2002 for

which a claim for priority under 35 U.S.C. § 120 has been made in the instant application and which contain the cited references of the present application. The disclosure statement is now in compliance with 37 C.F.R. § 1.98(d). Applicants respectfully request that the objection to the Information Disclosure Statement be withdrawn.

Election and Restrictions

Claims 49-60 have been objected to for lacking a common substantial structural feature or combination of features that distinguishes them as a group from related proteins in the art. Claims 15, 51 – 54, and 57-60 have been amended. Claims 1-4, 16-19, 22-27, 31 – 50, 55, and 56 have been canceled. The amendments obviate the basis of the rejection.

Objections to the Specification

The Office has objected to the specification for containing an embedded hyperlink or other browser-executable code. Applicants have amended paragraph [000230] to delete the embedded hyperlink and correct an obvious typographical error in the acronym "BLAST." The specification complies with the MPEP § 608.01(p). Applicants respectfully request that the objection to the specification be withdrawn.

Claim Objections

Claims 49-60 have been objected to for reciting an improper Markush group. The Office asserts that based upon Venter, et. al., (US Pat No. 5,344,776), the listing of DmGPCR1, DmGPCR5, DmGPCR7, and DmGPCR8 illustrates a lack of substantial structural features that distinguish them as a group from related proteins in the art. Claims 15, 51 – 54, and 57-60 have been amended. Claims 1-4, 16-19, 22-27, 31 – 50, 55, and 56 have been canceled. The amendments obviate the basis of the rejection. Applicants respectfully request that the claim objection be withdrawn.

Claim Rejection Under 35 U.S.C. §101

Claims 15, 19-21, and 55-60 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Applicants have amended claim 15 to recite "an isolated or recombinant" DmGPCR. The amendment obviates the basis for the rejection. Accordingly, Applicants respectfully request that the rejection of claims 15, 19-21, and 55-60 under 35 U.S.C. §101 as reciting non-statutory subject matter be withdrawn.

Claims 15, 19-21, 28-30 and 49-60 stand rejected under 35 U.S.C. §101 as not being supported by a specific and substantial utility. Applicants respectfully disagree.

Applicants note that to properly reject a claimed invention under 35 U.S.C. §101 where the asserted specific and substantial utility is not credible, the Office must make a *prima facie* showing that the claimed invention lacks utility with factual support and support such facts with a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. MPEP §2107.02 (IV) (See *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975). Applicants respectfully note that the Office has made a reasoned statement in the Office Action dated April 20, 2007, without providing any objective evidentiary support for its position. Rather, the Office makes mere conclusory statements about the predictability of the claimed invention. Failing to provide such evidentiary support, the rejection of claims 15, 19-21, and 55-60 is improper. Accordingly, the burden of evidence related to the credibility of the asserted utility has not shifted to Applicants. Applicants respectfully request that the rejection of claims 15, 19-21, 28-30 and 49-60 be withdrawn.

Notwithstanding the improper rejection of the claims, Applicants submit that he rejection is still improper.

To satisfy 35 U.S.C. §101, an invention must be useful. 35 U.S.C. §101 states:

> Whoever invents or discovers any ***new and useful*** process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefore, subject to the conditions and requirements of this title.

(emphasis added). The decision of the Court of Appeals for the Federal Circuit in *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999), is instructive in this regard. The claimed invention was directed to a "post-mix" beverage dispenser. In an action for infringement, summary judgment was granted in favor of the alleged infringer, based on the conclusion that the claimed invention lacked utility and was therefore unpatentable under 35 U.S.C. §101. The Federal Circuit reversed, relying on *Manson* for support. As noted by the Federal Circuit:

> The threshold of utility is ***not high***: An invention is useful under Section 101 if it is capable of providing ***some identifiable benefit***.

(51 USPQ2d at 1702; emphasis added).

The Utility Examination Guidelines were promulgated to assist Office personnel in their review of applications for compliance with the utility requirement under 35 U.S.C. §101. The Guidelines require that a claimed invention have a specific, substantial and credible asserted utility, or, alternatively a well-established utility that is immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

The claimed invention is supported by a specific, substantial and credible utility. Specific and substantial utilities that are credible are set forth in the application as filed. The present application is in compliance with the utility requirement.

The specification identifies credible specific and substantial utilities for the claimed invention. The specification identifies the utility of modulators of DmGPCRs as insecticides and as a treatment for ectoparasites. Each of the utilities asserted in the supporting written description of the present application is specific, substantial and credible. Further, each utility is well-established. The asserted utilities do not represent "throw-away," "insubstantial," or "nonspecific" utilities. Accordingly, those of skill in the art would readily agree that the claimed receptor was useful based in the characteristics of the invention set

forth in the supporting written description. The pending claims therefore comply with the requirements of 35 U.S.C. §101.

The claimed invention has at least one specific utility. The MPEP § 2107.01 states that a specific utility is "*specific* to the subject matter claimed." (italics in original). The utilities asserted in the supporting written description of the present specification are specific to the subject matter claimed. The claimed methods involve identification of modulators of receptor ligand interactions. Drosophila GPCR receptors are known to be important in numerous critical functions and they are used as targets for insecticides (see page 4 of the specification).

The claimed invention has a substantial utility. Section 2107.01 of the MPEP states that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." The use of the claimed methods are laboratory tools in experiments to identify insecticidal compounds provides a definite public benefit and, accordingly, provides a 'substantial' utility.

The utilities asserted by Appellants are credible. A person of ordinary skill in the art would conclude that the asserted utilities are "more likely than not true." (see MPEP § 2107.02).

Further the Guidelines comment on the use of computer based analysis of nucleic acids to assign functions to a nucleic acid or polypeptide based upon homology to sequences found in databases. Specifically, the Guidelines state that:

> [w]hen a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that

> the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no per se rule regarding homology, and each application must be judged on its own merits.

(Guidelines). "Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound." (MPEP § 2107.03 citing *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). That the "evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility" includes functional motifs provides compelling evidence that the same specific, substantial, and credible utility of the known receptors should be assigned to the compositions used in the present invention.

Furthermore, Applicants point out that further supporting evidence is not required either under 35 U.S.C. §101 or under the Utility Examination Guidelines. Requiring such supporting evidence would force those attempting to patent inventions in the biotechnological field to provide proofs not required in other fields of endeavor. The legal standard for utility is, and should be, the same in biotechnology as it is in other fields such as organic chemistry because these scientific fields entail the same degree of predictability in extrapolating from one compound or biological molecule to another. For example, just as proteins have secondary and tertiary conformations that may impart some particular properties to proteins, organic chemicals (e.g., small molecules) have steric requirements that may impart certain properties to those molecules. In chemical cases pharmaceutical utility is assumed for a

number of molecules with a common core structure and an R group pendant off the core structure (where R as a substituent can be any alkyl, aryl, amino, etc. group), even though utility is only shown, if at all, for one of this family of compounds. In fact, in many instances a mere statement of utility, speculated based upon structural analogy with a known compound which has the stated utility, is accepted as sufficient for organic chemicals. Accordingly, when a utility is known for one protein or polypeptide, utility should be assumed for the family of proteins that share a common biological function or structural characteristic. In the present case, the shared structural characteristic, as discussed above is two-fold. The claimed receptor shares sequence similarity as well as structural elements with proteins known to be useful.

The structural similarities, including ***both*** sequence identity and conserved motifs, between the claimed receptors and the known receptors, therefore, support Applicants' assertion of utility and would lead the art skilled to "conclude that the asserted utility is more likely than not true."

Claims 15, 21, 28 – 30, 51 – 54, and 57-60 are supported by a specific and substantial utility. Applicants respectfully request that the rejection of claims 15, 19-21, 28-30 and 49-60 under 35 U.S.C. §101 as not being supported by a specific and substantial utility be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 15, 19-21, 28-30, and 49-60 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to adequately teach how to use the instant invention. This rejection has been issued in combination with the rejection issued under 35 U.S.C. §101. Applicants traverse the rejection and respectfully request that the rejection be withdrawn.

As a preliminary matter, and as discussed above, the rejection of claims 15, 19-21, 28-30, and 49-60 was improperly issued under 35 U.S.C. § 101 for allegedly not containing specific and substantial credible utility. The Office does not provide any other reasoning in

the instant rejection to make up for the deficiencies in the above-mentioned reasoning of the 35 U.S.C. §101 rejection.

It is well established that the Office has the burden to provide reasoning and evidence in support of their position that would result in doubt of the objective truth of the statements provided in the specification. Without such a showing, the evidentiary burden on the examiner is not properly shifted to Applicants. Applicants respectfully contend that the Office has not met the requisite burden of evidence in view of the rejection based upon 35 U.S.C. § 112, first paragraph. Accordingly, the rejection is improper.

One skilled in the art at the time of filing would known how to use the claimed invention. The application is in compliance with the requirements of the first paragraph of section 112. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 19-21, 28-30, and 49-60 stand rejected under 35 U.S.C § 112, second paragraph allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention. Claims 15 and 28 have been amended to recite more precise subject matter. The amendment obviates the basis of rejection.

The application is in compliance with the requirements of the second paragraph of section 112. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

Claim 15 stands rejected under 35 U.S.C. 102(a) as allegedly being anticipated by Venter, *et. al.*, (US Pat No. 5,344,776) (hereinafter "Venter"). Applicants traverse the rejection and respectfully request that the rejection be withdrawn in light of the newly amended claim 15.

In order to anticipate the claims, the alleged prior art references must disclose, expressly or inherently, each and every limitation in the claims. Claim 15 has been amended to recite a method of binding an isolated or recombinant DmGPCR7 with a leucokinin (LK). Nowhere in Venter do authors disclose, teach, or suggest isolated or recombinant DmGPCR7, much less such a protein binding with a leucokinin. Therefore, Venter does not disclose, teach, or suggest all of the elements of the claims.

In view of the above discussion, the reference does not anticipate the claims. Applicants respectfully request that the rejections based upon 35 U.S.C. § 102(a) be withdrawn.

Claims 15, 19-21, and 55-60 stand rejected under 35 U.S.C. 102(a) as allegedly being anticipated by O'Donnell, *et. al.*, *Journal of Experimental Biology*, 1996, Vol. 199, pages 1163 – 1175 (hereinafter "O'Donnell"). Applicants traverse the rejection and respectfully request that the rejection be withdrawn.

In order to anticipate the claims, the alleged prior art references must disclose, expressly or inherently, each and every limitation in the claims. Claim 15 has been amended to recite isolated or recombinant DmGPCR7. Nowhere in O'Donnell do author disclose, teach , or suggest isolated or recombinant DmGPCRs, much less isolated or recombinant DmGPCR7. Therefore, O'Donnell does not disclose, teach, or suggest all of the elements of the claims.

In view of the above discussion, the reference does not anticipate the claims. Applicants respectfully request that the rejections based upon 35 U.S.C. § 102(a) be withdrawn.

Conclusion

Claims 15, 21, 28 – 30, 51 – 54, and 57-60 are in condition for allowance. Examination of the claims and their passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned attorney at 610.640.7855 to clarify any unresolved issues raised by this response.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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Date: October 22, 2007

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